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Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)

Conference of Radiation Control Program Directors, Inc

Prepared for

Bureau of Radiological Health, Rockville, Md

Jul 77

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CONFERENCE OF RADIATION CONTROL
PROGRAM DIRECTORS, INC.

GUIDES for NATURALLY OCCURRING and ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

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FDA 76-8048	Radiation Protection During Medical X-Ray Examinations - Part 4, Biological Effects of X Rays (National Audiovisual Center (GSA), Washington, D.C. 20409, $48.00).
FDA 76-8049	Radiation Protection During Medical X-Ray Examinations - Part 5, Gonad Shielding in Diagnostic Radiology (National Audiovisual Center (GSA), Washington, D.C. 20409, $39.00).
FDA 76-8051	Directory of Personnel Responsible for Radiological Health Programs (superseded by FDA 77-8016).
FDA 76-8052	Nationwide Evaluation of X-Ray Trends (GPO 017-015-00110-5, $0.35).
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FDA 76-8054	Specific Area Gonad Shielding - Recommendation for Use on Patients During Diagnostic X-Ray Procedures (GPO 017-015-00111-3, $0.45) (PB 258 039/AS, mf only).
FDA 76-8055	Diagnostic Ultrasound: A Review of Clinical Applications and the State of the Art of Commercial and Experimental Systems (GPO 017-015-00112-1, $1.45) (PB 258 237/AS, mf only).
FDA 76-8056	CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1975 (PB 257 937 AS, $6.75, $3.00 mf).

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Products containing naturally occurring and accelerator-produced radioactive material, other than uranium and thorium, are not subject to regulation by the U.S. Nuclear Regulatory Commission, nor are they comprehensively controlled by any other Federal agency. In the interest of uniform control for radioactive materials, the Conference of Radiation Control Program Directors, Inc., established a Task Force to develop guidance for the individual State's evaluation of NARM products. The Task Force consisted of representatives from State Radiation Control Programs, the BRH, the USNRC and the USEPA. The Bureau of Radiological Health funded the Task Force activities and provided the secretariat for the project. The NARM GUIDES set forth the relevant criteria for the evaluation of sources and products containing radioactive material. These GUIDES are intended to assist those persons or agencies interested in the uniform requirements governing the manufacture, assembly, and distribution of radioactive products.

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DIRECTOR, FDA/PRSC (NTIS)

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A Report of the Task Force

Prepared in support of
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Printed July 1977

Prepared by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
•
ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation Programs
•
U.S. NUCLEAR REGULATORY COMMISSION

and

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

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The mention of commercial products, their source, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products.

FOREWORD

The Conference of Radiation Control Program Directors is an organization whose membership is comprised of all directors of radiation control programs in the 50 States, the Territories, and some large municipal agencies. The Conference was formed to serve as a mechanism for providing a more functional means of exchanging information between State and Federal agencies as well as between States themselves in areas of mutual concern or interest. Additional objectives and purposes of this Conference are to:

1. Promote radiological health in all aspects and phases.
2. Encourage and promote cooperative enforcement programs with Federal agencies and between related enforcement agencies within each State.
3. Collect and make accessible to all radiation control program directors such information and data as might be of assistance to them in the proper fulfillment of their duties.
4. Foster uniformity of radiation control laws and regulations.
5. Support programs which will contribute to radiation control.
6. Assist members in their technical work and development.
7. Exercise leadership with radiation control professionals and consumers in radiation control development and action.

The Bureau of Radiological health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product radiation control program to protect the public health and safety.

The Bureau of Radiological Health, by contract and direct operations, supports the Conference of Radiation Control Program Directors in its objectives and activities for an action oriented Federal/State partnership to achieve and maintain comprehensive radiological health control. Selected reports of the Conference are published by the Bureau and are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, information services, industry, hospitals, laboratories, schools, the press, and other concerned individuals. These publications are for sale by the Government Printing Office and/or the National Technical Information Service.

Readers are encouraged to report errors or omissions to the Conference or the Bureau. Your comments or requests for further information are also solicited.

Gerald S. Parker
Chairman
Conference of Radiation Control
Program Directors, Inc.

John C. Villforth
Director
Bureau of Radiological Health

PREFACE

Products containing naturally occurring and accelerator-produced radioactive material, other than uranium and thorium, are not subject to regulation by the U.S. Nuclear Regulatory Commission, nor are they comprehensively controlled by any other Federal agency. In the interest of uniform control for radioactive materials, the Conference of Radiation Control Program Directors, Inc. established a Task Force to develop guidance for the individual State's evaluation of NARM products. The Task Force consisted of representatives from State Radiation Control Programs, the Bureau of Radiological Health, the U.S. Nuclear Regulatory Commission, and the U.S. Environmental Protection Agency. The Bureau of Radiological Health funded the Task Force activities and provided the secretariat for the project.

The NARM GUIDES set forth the relevant criteria for the evaluation of sources and products containing radioactive material. These GUIDES are intended to assist those persons or agencies interested in the uniform requirements governing the manufacture, assembly, and distribution of radioactive products.

This document should be of special interest to Federal, State, and local radiological health personnel in the United States and other countries.

Edgar D. Bailey

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Compliance and Inspection
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Peter Paras, Ph.D.
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*Suggested State Regulations for Control of Radiation

MEMBERSHIP

In 1975 the Conference of Radiation Control Program Directors established Task Force No. 1 to develop uniform guidance for the evaluation of NARM sources and products. Task Force No. 1, which prepared the NARM GUIDES, has the following membership:

Edgar D. Bailey, Chairman
Texas Department of Health Resources

James A. Blackburn
Illinois Department of Public Health

Eddie S. Fuente
Mississippi State Board of Health

Kirk Whatley
Alabama Department of Public Health

In addition, the following people served as resource persons to the Task Force:

For the Bureau of Radiological Health, FDA:

Allan C. Tapert, Secretary
Charles P. Froom

For the U.S. Environmental Protection Agency:

Joseph E. Fitzgerald, Jr.

For the U.S. Nuclear Regulatory Commission:

Edgar C. "Jim" Ashley
Walter Cool
Donovan A. Smith

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

INTRODUCTORY NARM GUIDE

A. Scope

NARM Guides provide uniform criteria for the evaluation of sources and products that incorporate naturally occurring or accelerator-produced radioactive materials (NARM). As used herein, NARM does not include byproduct, source, or special nuclear material. This Guide is a general introduction to NARM Guides 1 - 12 and presents background information and instructions on their use. NARM Guides 1 - 12 provide evaluative criteria for the following categories of sources and products:

GUIDE NO.	GUIDE TITLE
1.	Calibration and Reference Sources Containing Radium-226 for Distribution to Persons Generally Licensed Pursant to C.22(g), (SSRCR)*
2.	Sealed Sources
3.	Gas and Aerosol Detectors for Distribution to Persons Exempt from Regulation Pursuant to C.4(c) (3), SSRCR
4.	Measuring, Gauging, or Controlling Devices
5.	Radioactive Material for Distribution to Persons Exempt from Regulation Pursuant to C.4(b), SSRCR
6.	Static Elimination and Ion Generating Devices
7.	Radioluminous Products
8.	Electronic and Electrical Devices
9.	Leak Test Kits and Services
10.	Medical Sources
11.	Radiopharmaceuticals
12.	*In Vitro* Test Kits.

B. History

The manufacture, distribution, and use of NARM sources and devices are not covered by the Atomic Energy Act of 1954, as amended, and therefore are not regulated by the U. S. Nuclear Regulatory Commission. Rather, the regulation of NARM has been left to the discretion of each State. As such, the degree of regulation for NARM varies from State to State. To promote national uniformity, the Conference of Radiation Control Program Directors, Inc. in 1975 established a Task Force to develop uniform guidance for the evaluation of NARM sources and products. The Bureau of Radiological Health/FDA (BRH) funded Task Force activities. In support, the Bureau of Radiological Health, the Nuclear Regulatory Commission, and the Environmental Protection Agency participated in the deliberations of the Task Force.

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*Suggested State Regulations for Control of Radiation

C. Purpose

The NARM Guides are the basis of a program aimed at attaining unformity in the evaluation and distribution of NARM sources and products through the cooperative efforts of the States and the Federal agencies. These guides provide for the uniform classification and evaluation of NARM sources and products by radiation control agencies and are intended to be used in conjunction with the Radioactive Materials Reference Manual (RMRM) and the Suggested State Regulations for Control of Radiation (SSRCR).

D. Regulatory Process

Uniform application of the NARM Guides by radiation control agencies will promote radiological safety in the design and construction of NARM sources and products. Each NARM source or product intended for distribution in the United States shall be evaluated according to the appropriate NARM Guide prior to routine distribution.

A Licensing State should determine that each NARM source or product has been evaluated in accordance with the NARM Guides prior to licensing its possession and use. The issuance of a RMRM evaluation sheet is evidence that such an evaluation has been performed. The manufacture, assembly or distribution of NARM sources and products shall be licensed in Licensing States. In other States the appropriate authority shall issue a letter of authorization (or other document) for the manufacture, assembly, or distribution of a NARM source or product. The letter of authority shall set forth appropriate operating conditions which establish that the manufacture, assembly, or distribution of the NARM source or product will be performed in accordance with applicable provisions of the SSRCR and the relevant NARM Guide.

Prior to the issuance of the letter of authorization (or other document) the State shall assure, either by regulations or written agreements between the State and the manufacturer, assembler, or distributor that:

1. the State has the right to inspect the facilities, quality assurance and records of the manufacture, assembly, or distribution of the NARM source or product:
2. the manufacturer, assembler or distributor shall comply with the applicable requirements of the SSRCR; and
3. the manufacturer, assembler, or distributor shall meet the applicable provisions of the relevant NARM Guide.

E. Evaluation Process

The evaluation of NARM sources and products may be accomplished as follows:

1. State only - A State may, at its discretion, identify, evaluate, and prepare RMRM evaluation sheets on any NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction.
2. State with BRH assistance - A state may, at its discretion, request assistance from BRH for a cooperative evaluation (including preparation of RMRM evaluation sheet) of a NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction. This request shall be in writing.

3. BRH at the request of a State - A State may, at its discretion, request BRH to perform an evaluation (including preparation of RMRM evaluation sheet) of a NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction. This request shall be in writing.

The evaluating agency shall require the manufacturer, assembler, or distributor to submit in writing all information specified by the appropriate NARM Guide. In the event that a product or device contains a source which has previously been evaluated and included in the RMRM, no further evaluation of the source need be made provided the proposed source use is specific to that of the previously evaluated source.

A State shall not issue an RMRM evaluation sheet on a NARM source or product that is not acceptable for routine distribution under the suggested level of regulatory control.

A State shall not issue an RMRM evaluation sheet on a NARM source or product being manufactured in, assembled in, or distributed from another State.

F. Instructions for Completing and Submitting RMRM Sheets

The RMRM contains three types of sheets:

1. Evaluation (white sheets) - Indicates that an evaluation of the source or product has been made and recommends the suggested level of routine regulatory control to be applied to it, i.e., specific license, general license, or exemption. A suggested format for an evaluation sheet is shown in Appendix A.

2. Product Identification (green sheets) - Declares the existence of a NARM source or product for which an evaluation sheet does not exist. The radiation control agency noting the existence of the unevaluated NARM source or product shall issue a Product Identification sheet on it. If possible the State identifying the NARM source or product should notify the State of jurisdiction. A suggested format for a Product Identification sheet is shown in Appendix B.

3. Advisory Notice (pink sheets) - Advises of NARM source or product defects, misuses, or problems. The radiation control agency noting the defect, misuse, or problem shall issue an Advisory Notice sheet on it and notify the State of jurisdiction. A suggested format for an Advisory Notice sheet is shown in Appendix C.

Advisory Notices, Evaluations, and Product Identifications pertaining to NARM sources and products for distribution via the RMRM shall be sent to:

Director, Division of Radioactive Materials
and Nuclear Medicine (HFX 300)
Bureau of Radiological Health/FDA
5600 Fishers Lane
Rockville, Maryland 20857
Attention: Assistant Chief for Radioactive Products

BRH will duplicate and forward copies of each RMRM sheet to all States.

G. List of States by Degree of NARM Regulation

Basically there are three kinds of radiation control programs for NARM and other radioactive materials operated by the States. These are:

1. Agreement State - Licenses byproduct, source, and special nuclear material (agreement materials).
2. Licensing State - Licenses NARM.
3. Registration State - Registers NARM.

Licensing States

Alabama*
Arizona*
Arkansas*
California*
Colorado*
Florida*
Georgia*
Idaho*
Illinois
Kansas*
Kentucky*
Louisiana*
Maryland*
Michigan
Mississippi*
Nebraska*
Nevada*
New Hampshire*
New Jersey
New Mexico*
New York*
North Carolina*
North Dakota*
Oregon*
Pennsylvania
South Carolina*
Tennessee*
Texas*
Virginia
Washington*

*Also an Agreement State

Registration States

Alaska
Connecticut
Hawaii
Indiana
Maine
Massachusetts
Minnesota
Missouri
Ohio
Oklahoma
South Dakota
Utah
Vermont
West Virginia
Wisconsin
Wyoming

Other States

Delaware
  (issues permit)
District of Columbia
  (registers radium)
Iowa
  (no program)
Montana
  (registers radium)
Puerto Rico
  (no program)
Rhode Island
  (no program)
Virgin Islands
  (no program)

H. Availability of Documents Referenced in Guides

1. American National Standards Institute (ANSI) publications are available from:

American National Standards Institute
1430 Broadway
New York, New York 10018

2. "NARM Guides" are available from:

Director, Division of Radioactive Materials
and Nuclear Medicine (HFX-300)
Bureau of Radiological Health/FDA
5600 Fishers Lane
Rockville, Maryland 20857
Attention: Assistant Chief for Radioactive Products

3. National Council on Radiation Protection and Measurements (NCRP) reports are available from:

NCRP Publications
P. O. Box 30175
Washington, D. C. 20014

4. "Suggested State Regulations for Control of Radiation" (SSRCR) are available from:

Bureau of Radiological Health (HFX-25)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

I. Acknowledgment of Sources of Criteria

The Task Force in developing the NARM Guides liberally used requirements, standards and criteria from Regulations, Licensing Guides and Regulatory Guides of the U.S. Nuclear Regulatory Commission and the various States, reports by the National Council on Radiation Protection and Measurements and both draft and published standards of the American National Standards Institute.

J. Mechanism for Effecting Changes to Guides

Comments and recommendations regarding changes to these Guides should be sent to the Chairman, Conference of Radiation Control Program Directors via:

Director, Division of Radioactive Materials
and Nuclear Medicine (HFX-300)
Bureau of Radiological Health/FDA
5600 Fishers Lane
Rockville, Maryland 20857
Attention: Assistant Chief for Radioactive Products

APPENDIX A

Evaluation Sheet

(present information on following items)

Manufacturer

(name and address)

Distributor

(name and address)

Radioactive Material

(name and mass number)

Activity

(Curie sub-units)

Model Number

Use

Source/Device Description

physical appearance
describe construction
give results of prototype testing

Radiation Measurements

Quality Control

Include ANSI Classification as applicable

Labeling and Instructions

Licensing Recommendations

Evaluation by

(name and address of agency)

Note: See RMRM for sample

APPENDIX B

Product Identification Sheet

(present information on the following items)

Manufacturer
(name and address)

Distributor
(name and address)

Radioactive Material
(name and mass number)

Activity
(Curie sub-units)

Model No.

Use

Agency Making Identification
(name and address)

Note: See RMRM for sample.

APPENDIX C

Advisory Notice Sheet

TO: All Radiation Control Agencies

FROM: State of ________________________________

(Division of Radiological Health)

SUBJ: Product ____ Model ____ containing (name and mass number of NARM)

Give name and address of manufacturer, assembler, or distributor whose product or source has an actual or potential problem or defect.

State the problem, defect or misuse regarding the product, e.g.

radiation level
user instructions
wipe test results
malfunction
product labeling or mislabeling
packaging aspects

Specify the action to be taken on the problem to limit or correct any immediate or potential radiological hazard.

Note: See RMRM for sample.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 1

CALIBRATION AND REFERENCE SOURCES CONTAINING RADIUM-226 FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED PURSUANT TO C.22(g) SSRCR*

A. Scope

This Guide provides criteria for the evaluation of calibration and reference sources containing radium-226 for distribution to persons generally licensed pursuant to C.22(g) of the SSRCR. The sources subject to this guide are designed for use as radiation sources per se and not as a component within a device. These sources may be sealed sources or plated alpha sources.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Device - Any piece of equipment designed to utilize sealed source(s).
3. Plated alpha source - A source which has radioactive material plated, deposited or otherwise bonded to a rigid backing in such a manner as to prevent leakage or escape material (Ra-226).
4. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
5. Source holder - Mechanical support for the source.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of source for the evaluation of the source. Such information shall include:

1. Identification

Identify the source by model number or other specific model designation.

2. Proposed Use

Describe the proposed use and type(s) of radiation emitted from the source. Define or identify the environments and operating conditions expected during normal use. Indicate the expected useful life of the source.

3. Radioactive Material

Identify the radioactive material, maximum activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

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*Suggested State Regulations for Control of Radiation

4. Construction

Submit engineering drawings of the source identifying all materials of construction, dimensions and methods of sealing the source, if any. Submit drawings of the source holder, if any, identifying materials of construction, dimensions and methods for mounting the source in the holder.

5. ANSI Classification

State the American National Standards Institute (ANSI) classification designation for the source.

6. Labeling

Submit facsimiles of labeling or marking to be placed on each source and copies of instructions for use that will accompany the source.

7. Additional Information

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

Each source shall contain a quantity not to exceed 5 microcuries of radium-226.

E. Prototype Evaluation

The manufacturer, assembler, or distributor shall submit information including:

1. For any type of source which is designed to contain more than 0.005 microcurie of radium-226, prototype tests shall be conducted on each of five prototypes of such source in the following sequence:

   (a) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

   (b) Dry wipe test. The entire surface of the source shall be wiped with filter paper with the application of moderate pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper.

   (c) Wet wipe test. The entire surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried.

   (d) Water soak test. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by measuring the total radioactivity in the water in which the source was immersed.

   (e) Dry wipe test. On completion of the preceding tests (a) through (d) above, the dry wipe test described in (b) shall be repeated.

2. Removal of more than 0.005 microcurie of radioactivity in any test as prescribed in (a) through (e) above shall be cause for rejection of the source design. Results of prototype tests submitted shall be given in terms of microcuries and percent of removal from the total amount of radioactive material deposited on the source.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor should describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a dry wipe test upon each source containing more than 0.05 microcurie of radium-226 prior to transferring the source to a general licensee. This test shall be performed by wiping the entire surface of the source with a filter paper with the application of moderate pressure. The radioactivity on the filter paper shall be measured by using radiation detection instrumentation capable of detecting 0.0005 microcurie of radium-226. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing radium-226 and shall not be transferred to a general licensee.

G. Labeling and Instructions for Use of Sources

1. Each manufacturer, assembler, or distributor shall affix or attach to each source, source holder, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include, as a minimum, the following statement or a substantially similar statement:

> The receipt, possession, use and transfer of this source, Model ________, Serial No. _______, are subject to a general license and the regulations of Licensing States. Do Not Remove This Label.
>
> CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
> ________________ MICROCURIES RADIUM-226. DO NOT TOUCH
> (Specify quantity) RADIOACTIVE PORTION OF THIS SOURCE.
>
> ____
> (Name of manufacturer, assembler, or distributor)

2. Each distributor shall provide with each source:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within six (6) months of date of transfer.

   (b) A certificate of assay which gives the amount of activity, accuracy and date of assay for each source.

   (c) Instructions for the safe handling and usage of the source.

H. Transfer Reports

Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radium-226 transferred. The report shall identify the recipient by name and address, state the kinds and numbers of sources transferred, and specify the activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radium-226 have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Md., 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 2

SEALED SOURCES

A. Scope

This Guide provides criteria for the evaluation of all sealed sources containing radioactive material unless a more specific NARM Guide exists. The sealed sources subject to this Guide are designed for use as radiation sources per se or as a component within a device.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Device - Any piece of equipment designed to utilize sealed source(s).source(s).
3. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
4. Source holder - Mechanical support for the sealed source.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of sealed source for the evaluation of the sealed source. Such information shall include:

1. Identification

   Identify the source by type or model number or other specific model designation.

2. Proposed Use

   Describe the proposed use of the source. Define or identify the environments and operating conditions expected during normal use. Indicate the expected useful life of the source.

3. Radioactive Material

   Identify the radioactive material, maximum activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

4. Construction

   Submit engineering drawings of the source capsule identifying all materials of construction, dimensions and methods of sealing the source. Submit drawings of the source holder, if any, identifying materials of construction, dimensions and methods for mounting the source in the holder.

5. ANSI Classification

   State the American National Standards Institute (ANSI) classification designation.

6. Labeling

Submit facsimiles of the labeling to be engraved, etched, imprinted or printed on the sealed source, or on a tag to be attached to the source.

7. Additional Information

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

The manufacturer, assembler, or distributor shall submit information including:

1. Maximum radiation levels at 5 and 30 centimeters from any external surface of the source averaged over an area not to exceed 100 square centimeters, and the method of measurement or calculation;

2. Submit results of tests performed on prototype sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the source is likely to be subjected. These prototype tests should insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources," provided the means for assigning such a classification is described.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources" or "Leak-Testing Radioactive Brachytherapy Sources",as appropriate. Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie of radioactive material. In the case of radium-226 sources intended for brachytherapy, in addition to the above requirement, acceptability is indicated by a leakage rate of less than 0.001 microcurie of radon in 24 hours.

G. Labeling and Instructions for Use of Sources

1. Ideally, source labeling should include the words: "CAUTION -RADIOACTIVE MATERIAL," manufacturer's trademark or unique serial number, radionuclide, activity, assay date, and the radiation symbol. Where labeling the source is impracticable, a tag containing the above information should be attached to the source, unless the attachment of such a tag is also impracticable. When a sealed source is permanently mounted in a device, source labeling is not required provided the device is labeled as specified above.

2. Each distributor shall provide with each source:

(a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

(b) A certificate of assay for each source.

(c) Instructions for the safe handling and usage of the source.

H. Transfer Reports

1. Submission of transfer reports is not required for source(s) for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radioactive material transferred to persons generally licensed or exempt from regulations. The report shall identify the recipient by name and address, state the kinds and numbers of sources transferred, and specify the radionuclide and activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Md., 20857. The Bureau of Radiological Health will send copies of the report to all States.

NARM GUIDE 3

GAS AND AEROSOL DETECTORS FOR DISTRIBUTION TO PERSONS EXEMPT FROM REGULATION PURSUANT TO C.4(c)(3), SSRCR*

A. Scope

This Guide provides criteria for the evaluation of gas and aerosol detectors containing radioactive material which are to be distributed to persons exempt under C.4(c)(3) of the SSRCR. The gas and aerosol detectors covered by this Guide are only those designed to protect life or property from fires or airborne hazards.

B. Definitions

1. Device - Any piece of equipment designed to utilize sealed source(s).

2. Gas and aerosol detectors - Detectors, indicators, testers, and analyzers for gases, vapors, dusts, fumes, mists, and other airborne contaminants, products of combustion (both visible and invisible), and oxygen deficient atmospheres. As used in this Guide the term "detector" means the device with radioactive material incorporated into it.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of detector for the evaluation of the detector. Such information shall include:

1. Identification

Identify the radioactive source(s) and detector, respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the detector and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material(s), activity per source(s), chemical and physical form of the radioactive material(s), and the details of the method of incorporation and binding of the radioactive material(s) in the source(s).

4. Construction

(a) Submit engineering drawings of the detector identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material in the detector.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

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*Suggested State Regulations for Control of Radiation

5. Human Access

Describe the degree of access of human beings to the detector during normal handling and use.

6. Estimated Distribution

Submit an estimate of the total quantity of radioactive material to be distributed annually in this detector. This estimate will involve a market forecast for the detector.

7. Useful Life

Indicate the expected useful life of the detector.

8. ANSI Classification

State the American National Standards Institute (ANSI) classification designation.

9. Labeling

Submit facsimiles of the labelling or marking to be placed on each detector and manual that will accompany the detector.

10. Additional Information

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the detector.

D. Maximum Quantity

For detectors utilizing radium-226, the maximum quantity shall not exceed 0.1 microcurie.

E. Prototype Evaluation

1. A minimum of 2 prototype detectors shall be evaluated. Prototype detectors tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to material, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding or the safe operation of the detector requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the product averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the source is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

(c) Procedures for prototype testing of the detectors to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the detector.

(d) Results of the prototype testing of the detectors, including any change in the form of the radioactive material contained in the detector, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(e) A safety analysis based on the evaluation of the ability of the detector to withstand the normal conditions of handling, use, storage and disposal and the effects on containment and shielding of abnormally severe conditions of use and disposal, as well as fires and accidents which are likely to be encountered by the detector when used for its designed purpose. Aging effects are of particular importance.

(f) The estimated external radiation doses and dose commitments relevant to the safety criteria in Appendix A and the basis for such estimates.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of production lots of the detectors and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each detector by (a), or each production lot by (b), as shown below:

   (a) Applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

   (b) Performing an appropriate procedure given in (a) above in accordance with the Sampling Table in Appendix B. If any lot sampled in accordance with Appendix B includes a larger number of rejects than specified in Appendix B for a lot of that size, all detectors in that lot shall be sampled or the entire lot rejected.

G. Labeling and Instructions for Use of Detectors

The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler or distributor, and the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words "CAUTION - RADIOACTIVE MATERIAL". Disposal instructions shall be included on the label. The label or marking must be durable enough to remain legible for the useful life of the detector and be readily visible without disassembly of that part of the detector containing the radioactive material.

H. Transfer Reports

Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radioactive material transferred to persons exempt from regulations. The report shall state the kinds and numbers of detectors and sources transferred and specify the radionuclide and activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of NARM have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

Appendix A

SAFETY CRITERIA

The gas and aerosol detector shall be designed and manufactured so that:

1) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the detector, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ specified in column I below:[1]

	Column I (rem)	Column II (rem)	Column III (rem)
Whole body: head and trunk: active blood-forming organs: gonads; or lens of eye	0.005	0.5	15
Hands and forearms feet and ankles; or localized areas of skin averaged over areas no larger than one square centimeter	0.075	7.5	200
Other organs	0.015	1.5	50

It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the detector from wear and abuse likely to occur in normal handling and use of the detector during its useful life.

In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the detector, the probability is low that the containment, shielding, or other safety features of the detector would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the preceding table and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the preceding table.[1]

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[1] It is the intent that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used in estimating compliance with the criteria:

Low- not more than one such failure per year for each 10,000 exempt units distributed.
Negligible-not more than one such failure per year for each one million exempt units distributed.

Appendix B

SAMPLING TABLE

Lot size	Sample Size	Permissible number of rejects*
1-30	All	0
31-50	30	0
51-100	37	0
101-200	40	0
201-300	43	0
301-400	44	0
401-2000	45	0
2001-100,000	75	1

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* If any lot sampled in accordance with Appendix B includes a larger number of rejects than specified in Appendix B for a lot of that size, all detectors in that lot shall be sampled or the entire lot rejected.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 4

MEASURING, GAUGING, OR CONTROLLING DEVICES

A. Scope

This Guide provides criteria for the evaluation of measuring, gauging, or controlling devices, commonly called gauges, containing radioactive material.

The Suggested State Regulations for Control of Radiation (SSRCR) provide for the distribution of measuring, gauging, or controlling devices containing radioactive material to persons generally licensed pursuant to C.22(d) and to specific licensees.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Gauge - A device designed to utilize sealed source(s) for determining or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition.
3. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
4. Source holder - A device used to support and retain the source.
5. Source housing - The enclosure containing or incorporating the source, source holder and means for attenuation of the radiation.

C. General Criteria

The manufacturer, assembler, or distributor, shall submit sufficient information regarding each type or model of gauge for the evaluation of the gauge. Such information shall include:

1. Identification

Identify the radioactive source(s) and the gauge, respectively, by type, model number, or other specific model designation.

2. Proposed Use

Describe the proposed use of the gauge and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use as a component in other products, and circumstances of normal use. In addition, describe probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

3. Radioactive Material

(a) Identify the radioactive material(s), maximum activity per source, chemical and physical form of the radioactive material(s), the details of the method of incorporation and binding of the radioactive material(s) into the source, activity per source, and the number of sources in the gauge.

(b) Submit the information required by NARM Guide 2 - "Evaluation of Sealed Sources."

4. Construction

(a) Submit engineering drawings of the source housing, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the gauge during normal handling and use.

6. Useful Life

Indicate the expected useful lifetime of the gauge and of the source(s).

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation of the gauge. Also state the ANSI classification designation for the source(s).

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each gauge, and copies of the manual that will accompany the gauge.

9. Availability of Services

Submit information regarding the availability of the following services to the gauge user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance, and shutter checks;

(e) Source exchange;

(f) Emergency procedures; and

(g) Disposal.

Note: If the gauge is to be distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. Additional Information

Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the gauge.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. At least one gauge shall be evaluated. The prototype gauge tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe operation of the gauge requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor, shall submit information including:

   (a) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the gauge is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

   (b) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage including abrasion, corrosion, vibration, impact, puncture, compressive loads,and the probable effects on containment and shielding of abnormally severe conditions, such as explosion and fire. Aging effects are of particular importance. The results of testing which demonstrate that the gauge meets the designated performance classification according to the current ANSI Standard entitled "Classification of Industrial Radiation Gauging Devices" (currently in draft) shall also be submitted.

   (c) Submit radiation profiles (isodose curves e.g. 2 and 5 mR/h) of a prototype of the gauge with shutter(s) in the open and closed position(s). Radiation levels should be measured using the maximum activity of each kind of radioactive material expected to be used in the gauge. A description of the method used to measure the radiation levels should be included.

   (d) For gauges intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the gauge can be safely operated by persons not having training in radiological protection:

      (ii) under ordinary conditions of handling, storage, and use of the gauge, the radioactive material contained in the gauge will not be released or inadvertently removed from the gauge, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body: head and trunk; active
blood-forming organs; gonads; or
lens of eye . . . . 0.5 rem

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter . . . . 7.5 rems

Other organs . . . . 3.0 rems

(iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the gauge, it is unlikely that any individual would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . 15 rems

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter . . . . 200 rems

Other organs . . . . 50 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the gauge and the quality control standards for maintaining source design specifications. Also, if available, describe the quality assurance aspects and provide certificate(s) of compliance related to the gauge.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Gauge

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful life of the gauge and be readily visible.

2. For gauges intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

> The receipt, possession, use, and transfer of this device, Model______, Serial No. ______, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within six (6) months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe and efficacious usage of the source/device.

H. Transfer Reports

1. Submission of transfer reports is not required for gauge(s) distributed to specific licensees.

2. Each manufacturer, assembler, or distributor shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of gauge transferred, and the type and quantity of radioactive material contained in the gauge. If one or more intermediate persons will temporarily possess the gauge at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed pursuant to C.22(d) SSRCR during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NARM GUIDE 5

RADIOACTIVE MATERIAL FOR DISTRIBUTION TO PERSONS EXEMPT FROM REGULATION PURSUANT TO C.4(b), SSRCR*

A. Scope

This Guide provides criteria for the evaluation of exempt quantities of radioactive material for distribution to persons exempt from regulation pursuant to C.4(b) of the SSRCR.

B. Definitions

1. Exempt quantity - As used in this Guide, means that amount of radioactive material as listed in Schedule B, Part C, SSRCR (See Appendix A of the Guide). An exempt quantity may consist of one or more sources.

2. Source - As used in this Guide, means a processed chemical element, compound, or mixture, tissue sample, bioassay sample, counting standard, plated or encapsulated source, or similar substance.

C. General Criteria

The radioactive material can be considered for the exempt status providing:

1. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

2. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of source for the evaluation of the source. Such information shall include:

1. Identification

   Identify the radioactive source by model number or other specific model designation.

2. Radioactive Material

   Identify the radioactive material, activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

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*Suggested State Regulations for Control of Radiation

3. **Construction**

Submit engineering drawings of the source identifying all materials of construction, dimensions, and methods of sealing the source, if any.

4. **Labels and Instructions for Use**

Submit facsimiles of labeling or marking to be placed on each source and copies of instructions for use that will accompany the source.

5. **Additional Information**

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

1. The quantity of radioactive material per source shall not exceed that listed in Schedule B, Part C, of the SSRCR (See Appendix A of this Guide). These exempt quantities were determined by the method given in Appendix B.

2. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

E. Prototype Testing

Not applicable to this Guide.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lot(s) of the sources, as applicable, and the quality control standards for maintaining source design specification.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

G. Labeling and Instructions for Use

1. The immediate container for each exempt quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

   (a) identifies the radioactive material and the quantity of radioactivity, and

   (b) bears the words "Radioactive Material."

2. In addition, the label affixed to the immediate container, or an accompanying brochure, shall also:

   (a) state that the contents are exempt from Licensing State requirements;

(b) bear the words "Radioactive Material - Not for Human Use - Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not be Combined;" and

(c) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

H. Transfers and Transfer Reports

1. Each exempt quantity shall be separately and individually packaged. Not more than 10 such packaged exempt quantities shall be contained in any other package for transfer to persons exempt pursuant to C.4(b) SSRCR. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

2. Each manufacturer, assembler, or distributor, shall maintain records identifying, by name and address, each person to whom an exempt quantity is transferred. These records shall include the kinds and quantities of radioactive material transferred.

3. Each manufacturer, assembler, or distributor, shall file an annual summary report, in duplicate, with the State specifying the total quantity of each kind of radioactive material transferred. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

Appendix A

EXEMPT QUANTITIES*

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-71 (Ge 71)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine 135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100

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*Includes NARM and byproduct material.

Radioactive Material	Microcuries
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10

Radioactive Material	Microcuries
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

Appendix B

METHOD OF DETERMINING EXEMPT QUANTITIES OF RADIOACTIVE MATERIAL

Since inhalation is considered the most likely route of entry into the body, the quantity of radioactive material that would be inhaled by a standard man exposed for one year at the highest average concentration permitted in air for members of the general public in unrestricted areas is computed. Multiply the value given in the SSRCR, Part D, Appendix A, Table II, Column 1 concentration times 7.3×10^9 milliliters (ml/y). If the radionuclide emits gamma radiation, the quantity that, from a point source, would produce a radiation level of one milliroentgen per hour (mR/h) at a distance of ten centimeters is also computed. The smaller of these two quantities is then logarithmically rounded to the nearest decade, in microcuries. In the absence of published date on gamma emission, the following formula is used: $I = 0.156\ n\ E\ 10^5\ \mu_a$

Where $I\gamma$ = mR/hour at 1 meter per millicurie,
n = gamma quanta per disintegration,
E = energy of gamma quanta in MeV (million electron volts), and
μ_a = energy absorption coefficient for gamma in air.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 6

STATIC ELIMINATION AND ION-GENERATING DEVICES

A. Scope

This Guide provides criteria for the evaluation of static elimination devices and ion-generating tubes containing radioactive material. These products include lightning rods, brushes, precision balances, and other antistatic devices.

Since the Suggested State Regualtions for Control of Radiation, (SSRCR) do not provide for the exempt distribution or possession of static elimination devices and ion-generating tubes containing NARM, the distribution is limited to those persons generally licensed pursuant to C.22(d) or specific licensees.

B. Definitions

1. Device(s) - any piece of equipment which contains radioactive material designed for use as a static eliminator(s) or designed for the ionization of air.

C. General Criteria

The manufacturer, assembler, or distributor, shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

Identify the radioactive source(s) and the device, respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use. In addition, describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

(a) Submit engineering drawings of the device, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. **Human Access**

Describe the degree of access of human beings to the device during normal handling and use.

6. **Useful Life**

Indicate the expected useful life of the device.

7. **ANSI Classification Designation**

State the American National Standards Institute (ANSI) classification designation for the source.

8. **Labeling and Instructions for Use**

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. **Availability of Services**

Submit information regarding the availability of the following services to the device user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance, and shutter checks;

(e) Source exchange;

(f) Emergency procedures; and

(g) Disposal.

Note: If the device is to distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. **Additional Information**

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. **Maximum Quantity**

Not applicable for this Guide.

E. **Prototype Evaluation**

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, or shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the

results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor, shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

   (c) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage and use of the device.

   (d) Results of the prototype testing of the device, including any change in the form of the radioactive material contained in the device, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

   (e) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents. Aging effects are of particular importance.

   (f) For devices intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the device can be safely operated by persons not having training in radiological protection;

      (ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.5 rem
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	7.5 rems
Other organs	3 rems

      (iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . 15 rems

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter . . . . 200 rems

Other organs . . . . 50 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor, shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor, shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor, shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION—RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful like of the device and be readily visible.

2. For devices intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

   The receipt, possession, use, and transfer of this device, Model______, Serial No. ______, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. The manual shall provide procedures to be followed during packaging and shipping of the device. As a minimum, the procedures shall assure compliance with the packaging and shipping requirements of the U.S. Department of Transportation.

4. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe handling and usage of the device.

H. Transfer Reports

1. Submission of transfer reports is not required for device(s) for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of device transferred, and the type and quantity of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under C.22(d), SSRCR, during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 7

RADIOLUMINOUS PRODUCTS

A. Scope

This Guide provides criteria for the evaluation of radioluminous products containing radioactive material. These products include timepieces, instrument dials, luminous safety products, and other self-luminous light sources.

Since the Suggested State Regulations for Control of Radiation (SSRCR) do not provide for the exempt distribution is limited to those persons generally licensed pursuant to C.22(d) or specific licensees.

B. Definitions

1. Device - Any piece of equipment designed to utilize a radioluminous source.
2. Radioluminous source - A source consisting of a radioactive material firmly incorporated in solid and/or inactive material, or sealed in a protective envelope strong enough to prevent any leakage of the contained radioactive material to the environment under ordinary circumstances of use and incorporating a phosphor for the purpose of emitting light.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

Identify the radioactive source(s) and the device(s), respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

(a) Submit engineering drawings of the device, identifying all material of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the device during normal handling and use.

6. Useful Life

Indicate the expected useful life of the device.

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation of the source and the device if the device is classifiable by a current ANSI standard.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. Availability of Services

Submit information regarding the availability of the following services to the device user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance and shutter checks;

(e) Source exchange;

(f) Emergency procedure; and

(g) Disposal.

Note: If the device is to be distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. Additional Information

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, or shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources".

   (c) Results of tests performed on devices that establish the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device and as a minimum shall meet the designated usage classification according to current ANSI Standard entitled "Classification of Radioactive Self-Luminous Light Sources," provided the means for assigning such a classification is described.

   (d) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use, storage and disposal, and the effects on containment and shielding of abnormally severe conditions of use and disposal, as well as fires and accidents which are likely to be encountered by the device when used for its designed purpose. Aging effects are of particular importance.

   (e) For devices intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the device can be safely operated by persons not having training in radiological protection;

      (ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye.....	0.5 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	7.5 rems
Other organs	3 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor, shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor, shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor, shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount or radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL. The label or marking must be durable enough to remain legible for the useful life of the device and be readily visible.

2. For devices intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

   The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.
   (b) A certificate of assay for each source.
   (c) Instructions for the safe handling and usage of the device.

H. Transfer Reports

1. Submission of transfer reports is not required for devices for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor, shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, and individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of device transferred, and the type and quantity of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under C.22(d), SSRCR, during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 8

ELECTRONIC AND ELECTRICAL DEVICES

A. Scope

This Guide provides criteria for the evaluation of electronic and electrical devices containing radioactive material. These devices include electron tubes, fluorescent lamp starters, gas discharge lamps, vacuum tubes, electric lamps, germicidal lamps, piezoelectric ceramics, and spark gap irradiators.

Since the Suggested State Regulations for Control of Radiation (SSRCR) do not provide for the distribution of electronic and electrical devices containing NARM to persons exempt from regulation or to general licensees, the distribution is limited to specific licensees.

B. Definitions

1. Electron tube(s) - includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

2. Spark gap irradiator - a passive device, containing radioactive material attached near a spark gap to enhance reliability of ignition.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

Identify the radioactive source(s) and the device, respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe probable effects of severe conditions, including accidents or fires, and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

(a) Submit engineering drawings of the device, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the device during normal handling and use.

6. Useful Life

Indicate the expected useful life of the device.

7. ANSI Classification Designation

State the American National Standard Institute (ANSI) Classification designation for the source or device if applicable.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. Additional Information

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances, and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

(a) Maximum radiation level at 1 centimeter from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources".

(c) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, and use of the device.

(d) Results of the prototype testing of the device, including any change in the form of the radioactive material contained in the device, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(e) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents. Aging effects are of particular importance.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION-RADIOACTIVE MATERIAL". The label or marking must be durable enough to remain legible for the useful life of the device and be readily visible.

2. Each distributor shall provide with each source/device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe handling and usage of the source/device.

H. Transfer Reports

Not applicable to this Guide.

NARM GUIDE 9

LEAK TEST KITS AND SERVICES

A. Scope

This guide provides criteria for the evaluation of leak test kits and leak test services to be used for or in the assessment of leakage from sources of radioactive material.

B. Definitions

1. Leak test certificate - The written report of the analytical results of the leak test sample.

2. Leak test kit - Includes collection medium (filter paper, cotton swab, activated charcoal, etc.) and instruction for obtaining the test sample and for submitting it for analysis.

3. Leak test service - Includes the kit, analysis of test sample and reporting of results.

C. General Criteria

The leak test service company shall submit sufficient information to enable evaluation of each type of kit and service. Such information shall include:

1. Identification

Identify the kit by type and identification number or other specific model designation.

2. Proposed Use

Describe the proposed use of the kit and service.

3. Radioactive Material

Identify the type of radioactive material(s) for which the kit is designed to be used. Identify the type of radioactive material(s) for which the service is designed.

4. Description of Kit and Service

Identify the method of performing the leak test. Such tests shall meet or be equivalent to the tests specified in American National Standards Institute (ANSI) reports entitled "Classification of Sealed Radioactive Sources" and/or "Leak Testing Radioactive Brachytherapy Sources." The information to be submitted shall:

a) Describe in detail all components of the kit. Submit drawings or facsimilies of the kit.

b) Include copies of instruction for performing sample collection directly from the sources or elsewhere. In cases where the sample will not be taken directly from the source, drawings showing the proper site(s) for sample collection shall also be included. Instructions shall also be provided for returning the test sample to the leak test service company for analysis. These instructions shall include the performance of a radiation survey of the test sample for compliance with U.S. Department of Transportation or Postal Service Regulations.

c) Identify all instrumentation that will be used for analysis of the test samples. The identification shall include the manufacturer and model number of each instrument, the types and energies of detectable radiation, and the efficiency and minimum sensitivity of the instrument for each type of radioactive material to be tested and the frequency of calibration. As a minimum, the instrument must be capable of detecting 0.0005 microcurie of the radioactive material being tested or in the case of radium-226 brachytherapy sources, the leakage of radon-222 at the rate of 0.0001 microcurie per 24 hours.

d) Describe in detail the procedure for performing the analysis on the leak test samples.

e) Identify calibration standards to be used in the analysis of each material to be tested. Such standards shall be traceable to a National Standard.

f) Include sample calculations showing conversion from raw counting data to units of microcuries.

g) Include copies or facsimilies of leak test certificates. Such certificates shall identify (1) the name and address of the customer, (2) the date the sample was collected, (3) the individual collecting the sample, (4) the person performing the analysis, (5) the date the analysis was performed, (6) the unique identification of the source tested, (7) the radioactive material and mass number contained in the source, and (8) the result of the test expressed in microcuries. Actual test results shall be reported unless such results are less than 0.0005 microcurie or in the test for radon-222 leakage, 0.0001 microcurie per 24 hours.

5. Additional Information

Submit any additional information which will facilitate a determination of the adequacy of the kit and/or service.

D. Maximum Quantity

Not applicable to this Guide.

E. Prototype Evaluation

Not applicable to this Guide.

F. Quality Control

The leak test service company shall describe the quality control procedures to be followed in the evaluation of each leak test sample.

G. Instructions for Use

See Section C.4(b) of this Guide.

H. Records/Reports

A written report of the leak test results shall be furnished to the customer. In addition, immediate notification by telegraph or telephone shall be given to the customer for each leak test exceeding 0.005 microcurie; or in the case of radium-226 brachytherapy sources, those exceeding 0.001 microcurie of radon-222 per 24 hours.

The leak test service company shall maintain records of the results of each leak test analysis performed. These records shall include the information specified in C.4(g) of this Guide.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 10

MEDICAL SOURCES

A. Scope

This Guide provides criteria for the evaluation of medical sources containing radioactive material. These products include sources for brachytheraphy, anatomical markers, and bone mineral analysers. Distribution of these products is limited to specific licensees. This Guide does not include teletherapy units; as there are no known active manufacturers of NARM teletherapy units.

B. Definitions

1. Anatomical marker - a sealed radioactive source temporarily placed on the surface of the human body for reference location purposes in nuclear medicine imaging procedures.
2. Bone mineral analyser - a sealed radioactive source used for in vivo determination of the mineral content in bone.
3. Brachytherapy source - a sealed radioactive source used to deliver gamma or beta radiation at a distance up to a few centimeters for the treatment of disease. As used in this Guide, brachytherapy sources also include radioactive seeds, wires, and ribbons.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of source for the evaluation of the source. Such information shall include:

1. Identification

Identify the radioactive source(s) and device if applicable, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the source, and device, and identify the environments and application conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe the probable effects of severe conditions, including accidents or fires likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and if applicable the number of sources in the device.

4. Construction

(a) Submit engineering drawings of the source, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the source.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of application are clearly defined.

5. Human Access

For bone mineral analyzers describe the degree of access of human beings to the source during normal handling and use.

6. Useful Life

Indicate the expected useful life of the source and device.

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation for the source, if classifiable by a current ANSI standard.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each source, device, or tag attached to the source and copies of the manual that will accompany the source or device.

9. Additional Information

Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the source, or device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 sources (or devices) shall be evaluated. Prototype sources (or devices) tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe use of the source requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases it may be desirable to have tests carried out by qualified independent laboratories. Prototype evaluation of brachytherapy source(s) shall be performed according to the current ANSI standard entitled "Integrity and Test Specifications for Selected Brachytherapy Sources" if applicable.

2. The manufacturer, assembler, or distributor shall submit information including:

(a) Radiation levels:

(i) for bone mineral analyzers, the maximum radiation levels at 5 and 25 centimeters from any external surface of the source or package averaged over an area not to exceed 10 square centimeters, an evaluation of the patient absorbed dose per examination and the method of measurement.

(ii) for anatomical markers, the maximum contact dose rate for the surface in contact with the patient. This dose rate should be as low as reasonably achievable.

(b) Results of tests performed on sources that establish the integrity of the source under the most adverse conditions of use to which it is likely to be subjected. These prototype tests should, in sofar as possible, reflect the actual conditions of use and as a minimum shall meet the applicable designated usage classification according to the current ANSI standard entitled "Classification of Sealed Radioactive Sources" or "Integrity and Test Specifications for Selected Brachytherapy Sources", as appropriate

(c) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use, and storage, and the effects on containment and shielding of abnormally severe conditions of use and disposal, including fires and accidents. Aging effects are of particular importance.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the device and the quality control standards for maintaining device design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer shall perform a leak test on each sealed source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources" or "Leak Testing Radioactive Brachytherapy Sources", as appropriate. Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie of radioactive material. In the case of radium-226 sources intended for brachytherapy, in addition to the above requirement, acceptability is indicated by a leakage rate of less than 0.001 microcurie of radon in 24 hours.

4. Each manufacturer shall describe the procedure used to determine the linear distribution of the activity in the brachytherapy source. The linear distribution of the activity in each brachytherapy source shall meet design specifications.

G. Labeling and Instructions for Use of Source/Device

1. For anatomical markers and bone mineral analyzers, the label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful life of the source/device and be readily visible.

2. Brachytherapy sources should be labelled as recommended by the National Council on Radiation Protection and Measurements (NCRP Report No. 40).

3. Each distributor shall provide with each source/device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of the date of transfer.

   (b) A certificate of calibration for each brachytherapy source as recommended by the National Council on Radiation Protection and Measurements (NCRP) Report No. 41).

   (c) Instructions for the safe and efficacious usage of the source/device.

H. Transfer Reports

Not applicable to this Guide.

NATURALLY OCCURING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 11

RADIOPHARMACEUTICALS

A. Scope

Radiopharmaceuticals, including medical radionuclidic generators and reagent kits, intended for distribution are drugs and, as such, are subject to evaluation and regulation by the U.S. Food and Drug Administration. The manufacturing and distribution, however, are subject to the regulations of the State. The State should not authorize distribution or medical use of these products until the manufacturer demonstrates compliance with the requirements of the U.S. Food and Drug Administration for the product and the U.S. Department of Transportation for the shipping container(s).

B. Definitions

1. Radiopharmaceutical - a pharmaceutical containing radioactive material intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.
2. Radionuclidic generator - a source in which a daughter radionuclide is eluted from an ion exchange column containing a parent radionuclide where the eluate may be used as a radiopharmaceutical.
3. Reagent kit - a package containing necessary components (none of which need be radioactive) designed to formulate a finished dosage form of a radiopharmaceutical.

C. Reference Transmittals

Upon written request the Bureau of Radiological Health, Food and Drug Administration shall provide to the respective State the following information on specified radiopharmaceuticals:

1. An abbreviated summary of FDA approved radiopharmaceutical drug products.
2. Listings of clinical investigators for investigational new drugs supplied by commercial sponsors.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 12

IN VITRO TEST KITS

A. Scope

This Guide provides criteria for the evaluation of in vitro test kits containing radioactive material. The Suggested State Regulations for Control of Radiation (SSRCR) provide for the distribution of in vitro test kits containing radioactive material to persons exempt from regulation pursuant to C.4(b), to persons generally licensed pursuant to C.22(i), and to specific licensees.

B. Definitions

In vitro test kit (kit) - a package containing the necessary components, at least one of which is radioactive, to perform clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of kit for the evaluation of the kit. Such information shall include:

1. Identification

Identify the kit by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the kit and identify the environments and application conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe the probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, activity per vial or test unit, and the number of vials or test units per kit or package.

4. Construction

(a) Submit engineering drawings of the kit, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the kit or package.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of application are clearly defined.

5. Human Access

Describe the degree of access of human beings to the radioactive material during normal handling and use.

6. **Useful Life**

Indicate the expected useful life of the kit.

7. **ANSI Classification Designation**

Not applicable to this Guide.

8. **Labeling and Instructions for Use**

Submit facsimiles of the labeling or marking to be placed on each vial or test unit and the kit package and copies of the instructions for use, storage, and disposal that will accompany the kit.

9. **Additional Information**

Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the kit.

D. **Maximum Quantity**

1. For kits intended for distribution to persons exempt from regulation pursuant to C.4(b) SSRCR, the quantity of radioactive material per kit shall not exceed that listed in schedule B, Part C, SSRCR. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

2. For kits intended for distribution to persons generally licensed pursuant to C.22(i), SSRCR, the quantity of radioactive material per each separately prepackaged unit shall not exceed 10 microcuries of cobalt 57.

3. For kits intended for distribution only to persons specifically licensed, a maximum quantity per kit is not applicable.

E. **Prototype Evaluation**

1. A minimum of 2 kits shall be evaluated. Prototype kits tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe use of the kit requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation level at any external surface of the package averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on kits that establish the integrity of the kit construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use.

   (c) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents.

(d) For kits intended for distribution to persons exempt from regulation pursuant to C.4(b), or to persons generally licensed pursuant to C.22(i), sufficient information to provide reasonable assurance that the kit can be safely used by persons not having training in radiological protection.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the kits and the quality control standards for maintaining kit design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the kit. The assay shall be traceable to a National Standard.

G. Labeling and Instructions for Use of Kit

1. The label shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words "CAUTION - RADIOACTIVE MATERIAL" and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS". A readily visible label shall appear on each prepackaged unit and must be durable enough to remain legible for the useful life of the kit.

2. For kits intended for distribution to persons exempt for regulation pursuant to C.4(b), in addition to the labeling information required by (1) above, the label affixed to the prepackaged unit or an accompanying brochure, shall:

   (a) state that the contents are exempt from Licensing State requirements;

   (b) bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined";

   (c) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. For kits intended for distribution to persons generally licensed pursuant to C.22(i), in addition to the labeling information required by (1) above, the label affixed to the prepackaged unit, or an accompanying brochure, shall contain the following statement or a substantially similar statement:

> This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State. ____________________
>
> Name of Manufacturer

4. In addition to the specific labeling required in 1, 2, and 3 above, the label or accompanying brochure shall contain adequate information as to the precautions to be observed in handling,storing, and disposing of the radioactive material.

H. Transfer Reports

1. Submission of transfer reports is not required for kits distributed to general or specific licensees.

2. For kits transferred to persons exempt from regulation pursuant to C.4(b);

   (a) Each kit shall be separately and individually packaged. Not more than 10 such packaged kits shall be contained in any outer package. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

   (b) Each manufacturer, assembler, or distributor shall maintain records identifying, by name and address, each person to whom a kit is transferred. These records shall include the kinds and quantities of radioactive material transferred.

   (c) Each manufacturer, assembler, or distributor shall file an annual summary report, in duplicate, with the State specifying the total quantity of radioactive material transferred. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

RATIONALE FOR NARM GUIDES

July 3, 1977

INTRODUCTORY NARM GUIDE

Products containing naturally occurring radioactive materials, primarily radium, have been used for consumer, industrial or medical applications since the early 1900's. Accelerator-produced radioactive materials have impacted on the marketplace within the past decade. Naturally occurring and accelerator-produced radioactive materials are collectively referred to as NARM. The population exposed to radiation from NARM products consists of millions of people. Most of these people are members of the general public who have consumer products that are radioactive and present a minimal degree of radiation exposure to the individual. Personnel working in medical and industrial facilities are also exposed to radiation from NARM sources and devices.

Since NARM is not comprehensively controlled by the Federal Government, the regulation of NARM has been left to the discretion of each State. To promote national uniformity, the Conference of Radiation Control Program Directors (CRCPD) established a Task Force in 1975 to develop uniform guidance for evaluation of NARM sources and products. The members of the Task Force included representatives of the CRCPD, Bureau of Radiological Health/FDA, Nuclear Regulatory Commission, and the Environmental Protection Agency. The Bureau of Radiological Health/FDA funded the Task Force activities. These Guides are compatible with existing guidance and procedures developed by the Nuclear Regulatory Commission (NRC) for other radioactive materials, e.g., byproduct and source materials. The Guides reflect recommendations and suggestions of the American National Standards Institute (ANSI) and the National Council on Radiation Protection and Measurements (NCRP). Also, the manufacturer is requested to describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

The NARM Guides classify NARM sources or products into 12 categories and provide criteria for evaluating a given NARM product regarding (1) manufacturer identification and model number, (2) results of radiation measurements, (3) labelling of name and amount of radioactive material, and (4) licensing recommendation for product control. The "Introductory NARM Guide" also presents a format on the "regulatory process" to appropriately control the manufacture, assembly, distribution, and use of a NARM product in conjunction with the Suggested State Regulations for Control of Radiation (SSRCR) and Radioactive Materials Reference Manual (RMRM).

NARM GUIDE NO. 1 - Calibration and Reference Sources Containing Radium-226 for Distribution to Persons Generally Licensed Pursuant to C.22(g), SSRCR

B. Definitions

The basis for the definitions of "Capsule," "Device" and "Source holder" is ANSI Report N5.10 - 1968. The definition of "Sealed source" is based on the definition given for this item in Title 10, Code of Federal Regulations, 10 CFR 34.2 (e). The definition for "Plated alpha source" is similar to the definition of "Sealed source" in the SSRCR; since a "Plated alpha source" is a matrix form designed to prevent the leakage and dispersal of radioactive material.

C. General Criteria

The request for information on the NARM product regarding its identification, use, construction, ANSI classification and labelling provide a reference basis for the radiological evaluation of the product. The description, function, and use of the source/device is to be clearly stated. From this information and its subsequent evaluation, the control agency can determine that the source/device may be used safely within regulations of the Agency or provisions of the SSRCR.

D. Maximum Quantity

The rationale for specifying five microcuries as the maximum quantity of a calibration or reference source incorporating radium-226 is that five microcuries is a usable quantity applied in the common practice of standardizing radiation survey instruments, and that use of this quantity over many years has attested to its acceptability. The maximum quantity allowed by C.22(g)(5)(i) SSRCR for americium-241 (10 CFR 31.8(c)(1)), plutonium (10 CFR 70.19 (c)(1)) and radium-226 is five microcuries in such sources.

E. Prototype Evaluation

The reason for performing items E.1(a) - (e) in that given order is because C.28(f) SSRCR requires the applicant to satisfy the general provisions of 10 CFR 70.39 which in turn requires that the five prototype tests be conducted in this sequence.

In item E.2, 0.005 microcurie of radioactivity has been specified as the leak test limit; since it has been a long standing practice by industry and regulatory agencies to accept this limit. It is cited extensively throughout NRC regulations and ANSI standards, e.g., 10 CFR 32.59 and N44.2 - 1973.

F. Quality Control

The rationale for specifying 0.0005 microcurie (item F.3) as the lower limit of instrumentation detection is that the concept of the instrumentation as being capable of detecting one order of magnitude less than the specified removable radioactivity contamination limit is recommended by ANSI N44.1 - 1973. Such instrumentation is readily available on the market.

NARM GUIDE NO. 2 - Sealed Sources

E. Prototype Evaluation

Measurements at the distances of 5 and 30 centimeters from any external surface of the source averaged over an area of 100 square centimeters for determination of maximum radiation levels are specified in item E.1. The distance of 5 centimeters satisfies the geometry limitations in the practical use of many radiation survey instruments. The distance of 30 centimeters approximates 12 inches cited in D.204(a) SSRCR (10 CFR 20.204(a)). ANSI N43-3.2 (draft 9/24/76) specifies 100 square centimeters as the maximum area for averaging radiation measurements. Radiation instruments meeting this criterion are commonly available; therefore, special instruments are not required.

F. Quality Control

The basis for the leakage rate of less than 0.001 microcurie of radon in 24 hours for radium-226 sources intended for brachytherapy (item F.3) is that paragraph 3.2.2 of ANSI N44.2 - 1973 specifies this leak test criterion of 1 nanocurie (0.001 microcurie) in 24 hours for radon.

H. Transfer Report

The rationale for not requiring transfer reports (item H.1) for sources distributed only to specific licensees is not a contradiction of A.4 SSRCR which requires that licensees (e.g., manufacturers) maintain records for the receipt, transfer and disposal of all radiation sources. In this case, persons who use the radiation source are specific licensees; hence, are known to, and routinely inspected by, the authorizing agency. There is no further need to identify specifically licensed source/device recipients.

NARM GUIDE NO. 3 - Gas and Aerosol Detectors for Distribution to Persons Exempt from Regulation Pursuant to C.4(c)(3) SSRCR

B. Definitions

The definition of "Gas and aerosol detector" (item B.2) is taken from AEC Licensing Guide - Exemption of Gas and Aerosol Detectors Containing Byproduct Material, dated October 10, 1969, which applies to the exemption of gas and aerosol detectors containing byproduct material.

C. General Criteria

The reason for requesting descriptions of the types of users, locations of use, possibilities of use in other products and circumstances of normal use (item C.2) is that these data are necessary for evaluation of the detector. Further, this language tends to promote uniformity with the NRC regulation and licensing guides for gas and aerosol detectors containing byproduct material.

An example of a special design feature (item C.4(b)) is a one-way screw or other access limiting tool which may be incorporated in the device.

The kinds of information requested in items C.6 and C.7 can be used to estimate the amount of radioactive material to ultimately be disposed to the environment and allow regulatory agencies to anticipate potential problems.

D. Maximum Quantity

The rationale for specifying a maximum quantity of 0.1 microcuries of radium in gas and aerosol detectors (item D) is that this amount is consistent with the Nuclear Energy Agency draft standard, April 1976, on ionization chamber smoke detectors intended for unrestricted distribution.

E. Prototype Evaluation

The basis for specifying a minimum of two prototype detectors (item E.1) for evaluation is given in the test specification procedures for evaluating brachytherapy sources in ANSI N44.1 - 1973. It may be advisable to have an independent evaluation performed by an outside laboratory under certain circumstances. These kinds of tests are also required of byproduct devices in AEC Licensing Guide - Exemption of Gas and Aerosol Detectors Containing Byproduct Material dated October 10, 1969 (See item B.2 of NARM Guide 3).

The distances of 5 and 25 centimeters from any external surface of the detector averaged over an area not to exceed 10 square centimeters for determination of the maximum radiation levels are specified in item E.2(a). These distances and this area are specified in 10 CFR 32.26(b)(6) by the NRC for similar detectors containing byproduct material. The rationale for requesting information on aging effects (item E.2(e)) is based on the requirement for gas and aerosol detectors containing byproduct material in the above referenced AEC licensing guide dated October 10, 1969.

APPENDICES

Appendix A for this Guide is based on NRC regulations regarding gas and aerosol detectors containing byproduct material in 10 CFR 32.27-28. Appendix B comes from 10 CFR 32.110 on "Acceptance sampling procedures under certain specific licenses."

NARM GUIDE NO. 4 - Measuring, Gauging or Controlling Devices

B. Definitions

The definition of "Gauge" (item B.2) is based on the provision given in C.22(d)(1) SSRCR and in 10 CFR 31.5(a).

C. General Criteria

The rationale for requesting information (item C.9) on the kinds of services available to the gauge user is in order for the agency to view the entire use range. Further, generally licensed gauges are transferred without prior agency evaluation of the recipients' training and experience. These kinds of services are required by C.22(d) of the SSRCR and 10 CFR 31.5.

E. Prototype Evaluation

The basis for requesting that at least one gauge be evaluated (item E.1) is that it is consistent with current practice as recommended in the ANSI N-538 - 1976 draft report on gauging devices.

The request for information (item E.2(d)(i)) that the gauge can be operated safely by persons not trained in radiation protection is consistent with the requirement C.28(d)(1)(ii)(a) of the SSRCR and 10 CFR 32.51 (a)(2)(i).

H. Transfer Reports

As some gauge systems are "turn key" operations there is a need to identify persons who only temporarily possess the gauge (item H.2). The identification of persons who possess the gauge temporarily, or otherwise, is consistent with the requirements of 10 CFR 32.52(a) and (b) as well as C.28(d)(4) of the SSRCR.

NARM GUIDE NO. 5 - Radioactive Material for Distribution to Persons Exempt from Regulation Pursuant to C.4(b) SSRCR

D. Maximum Quantity

The rationale for specifying a maximum limit of 10 exempt quantities (item D.2) is based on the requirement of C.28(b)(2) of the SSRCR (10 CFR 32.19 (a)).

H. Transfers and Transfer Reports

The reason for specifying the limit of 0.5 millirem per hour at the surface (item H.1) of a package containing radioactive material is based on the requirement of C.28(b)(2)(ii) of the SSRCR (10 CFR 32.19(b)) regarding this matter.

APPENDICES

The method of determining exempt quantities in Appendix B was given in an AEC memorandum from F. Western to E. Price dated February 6, 1968. The method later appeared in a statement of consideration for proposed rulemaking; Federal Register Vol. 33, page 11414, August 10, 1968.

NARM GUIDE NO. 6 - Static Elimination and Ion Generating Devices

B. Definitions

The definition of "Device" given in item B.1 of this Guide is different from the definition for "Device" cited in NARM Guides 1, 2 and 3; since the equipment addressed by Guide 6 may not contain a sealed source. Hence, the Guide 6 definition of "Device" is not applicable to NARM Guides 1, 2 or 3.

E. Prototype Evaluation

The rationale for requesting a minimum of two devices for evaluation is consistent with ANSI N44.1 - 1973.

NARM GUIDE NO. 7 - Radioluminous Products

B. Definitions

The definition of "Device" given in item B.1 of this Guide is different from the definition for "Device" cited in NARM Guides 1, 2, or 3; since the equipment addressed by Guide #7 may not contain a sealed source. Hence, the Guide #7 definition of "Device" is not applicable to NARM Guides 1, 2, or 3.

The definition, "Radioluminous product," (item B.2) is based on the definition for "self-luminous light source" given in the ANSI N540 - 1975 report entitled Classification of Radioactive Self-Luminous Light Sources.

E. Prototype Evaluation

The rationale for requesting a minimum of two samples of the radioluminous product for evaluation (item E.1) is consistent with paragraph 4.2 of ANSI N540 - 1975. The rationale for specifying maximum radiation levels of 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters is cited from 10 CFR 32.22 (a)(2)(vi) for self-luminous products.

NARM GUIDE NO. 8 - Electronic and Electrical Devices

B. Definitions

The definition for "Electron tube" (item B.1) was taken from footnote 3 of C.4(c)(1)(vii) of the SSRCR and 10 CFR 30.15(a)(8). The definition of

"Spark gap irradiator" (item B.2) is based on the NRC definition of "Spark gap irradiator" given in the rulemaking proposal which appeared in 40 FR 49801, October 24, 1975.

E. Prototype Evaluation

The rationale for requiring a distance of 1 centimeter and a maximum rate of 1 millirad per hour measured through an absorber density of 7 milligrams per square centimeter is that these same factors are required by C.4(c)(1) SSRCR (10 CFR 30.15 (a)(8)).

The specification of the area of 10 square centimeters for averaging radiation level measurements is consistent with this same value cited previously for NARM Guides 3 and 7.

NARM GUIDE NO. 9 - Leak Test Kits and Services

B. Definitions

The definitions of "Leak test certificate," "Leak test kit," and "Leak test service" (items B.1, B.2, and B.3, respectively) were derived from Task Force consensus.

C. General Criteria

The rationale for specifying 0.0001 microcurie (item C.4(c)) as a minimum detection limit of the instrumentation used for measuring the radon-222 leakage from a radium-226 test sample is that this magnitude is recommended in paragraph 5.4 of ANSI N44.1 - 1973. Further, it is the consensus of the Task Force that instrumentation should be capable of detecting one order of magnitude less than the specified leakage rate limit for radon-222. Such instrumentation is readily available on the market. The rationale for specifying 0.0005 and 0.0001 microcurie (item C.4(g)) as the lower limits for the reporting of test results is that these values have been specified as the lower sensitivity limits of the instrumentation used for measuring radioactive contamination and leakage. Hence, any measured activity equal to or exceeding these values should be reported.

NARM GUIDE NO. 10 - Medical Sources

B. Definitions

The definitions of "Anatomical marker," "Bone mineral analyzer," and "Brachytherapy source" (items B.1, B.2, and B.3, respectively) were developed by the Task Force.

NARM GUIDE NO. 11 - Radiopharmaceuticals

B. Definitions

The definitions of "Radiopharmaceutical," "Radionuclidic generator," and "Reagent kit" (items B.1, B.2, and B.3, respectively) were developed by the Task Force.

NARM GUIDE NO. 12 - In Vitro Test Kits

B. Definitions

The definition of "In vitro test kit" (item B) is based on C.22(i) of the SSRCR and 10 CFR 31.11(a).

D. Maximum Quantity

The basis for exempting a quantity composed of fractional parts provided that their sum does not exceed unity (item D.1) is C.28(b)(2) of the SSRCR. The reason for limiting the maximum amount of cobalt 57 to 10 microcuries per kit (item D.2) is that this limit is given for cobalt 57 in C.22(i)(1)(vi) of the 1976 Revision of the SSRCR.

H. Transfer Reports

The transfer limit (item H.2(a)) to persons exempt from regulation (pursuant to C.4(b) SSRCR) of no more than 10 kits contained in any outer package with a dose rate not exceeding 0.5 millirem per hour at the external surface of the package comes from C.28(b)(2)(ii) of the SSRCR (10 CFR 32.19(b)).

The ABSTRACT CARDS below are designed to facilitate document retrieval using Coordinate Indexing. They provide space for an accession number (to be filled in by the user), suggested keywords, bibliographic information and an abstract.

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Accession No.

Prepared by: Conference of Radiation Control Program Directors, Inc., Environmental Control Agency, Office of Radiation Programs; U.S. Nuclear Regulatory Commission; and USDHEW/PHS/FDA/BRH. GUIDES for NATURALLY OCCURRING and ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM).

U.S. Department of Health, Education, and Welfare, PHS, FDA, Bureau of Radiological Health - HEW Publication (FDA) 77-8025 (Printed July 1977) 78 pp. (limited distribution).

ABSTRACT: The Bureau of Radiological Health, FDA, funded a Task Force of the Conference of Radiation Control Program Directors, Inc., under contract PHS 223-76-6018, to develop guidance for the individual State's evaluation of NARM products, since products containing

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FDA 76-8058	Quadrennial Report of the Division of Biological Effects (PB 258 436/AS $6.75).
FDA 76-8061	Uranium in Dental Porcelain (GPO 017-015-00113-0, $1.00) (PB 259 624/AS, mf only).
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FDA 77-8016	Directory of Personnel Responsible for Radiological Health Programs (superseded by FDA 77-8027).
FDA 77-8017	Nationwide Evaluation of X-Ray Trends: Organ Dose Index System - Radiographic Field Survey Procedures Handbook (GPO 017-015-00121-1, $0.80).
FDA 77-8018	Photographic Quality Assurance in Diagnostic Radiology, Nuclear Medicine, and Radiation Therapy. Volume II - Photographic Processing, Quality Assurance and The Evaluation of Photographic Materials (GPO 017-015-00123-7, $2.20).
FDA 77-8020	Patient Exposure from Diagnostic X Rays: An Analysis of 1972-1974 NEXT Data (PB 267 741/AS, $4.00).
FDA 77-8021	8th Annual National Conference on Radiation Control: Radiation Benefits and Risks: Facts, Issues, and Options (PB 267 317/AS, $11.75).
FDA 77-8023	Radiological Health Training Resources - 1977.
FDA 77-8025	Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM).

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